REMARKS

Claims 1 - 16 are pending and stand rejected. The Examiner has made a number of rejections based on Donson ('931 patent) and Untermohlen ('976 patent). In addition, the Examiner has raised double patenting rejections and formal rejections of the claims pursuant to 35 U.S.C. 112.

A. Formal Rejections

The Examiner rejects Claims 1, 4-9 and 12-16 under 35 U.S.C. 112 as allegedly indefinite. Without acquiescing to the rejection, but to further the prosecution, the claims have been amended to address the antecedent basis issues raised by the Examiner.

Claim 1 has also been amended in view of the Examiner's assertions regarding "significant interference." Without agreeing with the Examiner, and expressly reserving the right to prosecute claims with similar language in the future, the language referred to in Claim 1 has been deleted, rendering the rejection moot.

B. The Examiner Use Of the '931 Patent Is Not Supported

The Examiner first employed the '931 patent as a basis for a rejection in an Office Action dated 12/04/2001. In response dated 06/04/2002, it was noted that the Examiner has the initial burden to show that the '931 patent is entitled to an earlier date than the filing date of July 31, 1992.

Over one and one half years later, the Examiner has still not satisfied this burden. It is worth noting some undisputed facts. It is undisputed that the July 31, 1992 filing was a continuation-in-part of Ser. No. 600,244. Continuation-in-part applications by definition contain new matter. The question is: why is the Examiner treating the July 31, 1992 filing as a mere continuation application?

Of course, the Examiner might very well find a passage of text that is precisely carried over into the CIP filing. But this is not the case. The Examiner merely asserts that "The disclosure of the CIP parent document provides support for the disclosure in the child document US 5,316, 931 (Donson et al.)." (Office Action dated 10/22/2003, page 4).

On what basis does the Examiner conclude that there is "support"? The Examiner points to "relevant passages in the specification" of the parent. (Office Action dated

10/22/2003, page 9). But when one looks carefully at these passages in the parent specification, one sees that they are NOT what the Examiner says they are. Moreover, the Examiner makes no effort to show that the text of these passages can be found in the '931 specification.

For example, the Examiner points to two passages in the parent specification as allegedly teaching "nucleic acid encoding a foreign peptide *inserted* into a viral nucleic acid encoding a viral coat protein" (Office Action dated 10/22/2003, page 9, emphasis added). The first passage offered by the Examiner is on page 11, lines 27-35 (lines 27-32 are shown below):

> "The first step in achieving any of the features of the invention is to modify the nucleotide sequences coding for the capsid protein and any transmissibility factors within the viral nucleotide sequence by known conventional techniques such that non-biologically functional proteins are produced by the modified virus."

Where in this passage is there anything regarding insertion of a foreign peptide? It does not exist.[1] The passage teaches the modification of the capsid to *destroy* biological function of the proteins, *i.e.* destroy the function of the coat protein. This is the opposite of what the present claims are directed to, *i.e.* insertion into the native protein.[2]

The second passage pointed to by the Examiner is page 25, lines 13-35 (lines 13-27 are shown below):

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[1] Whether by innocent misunderstanding of the science or not, misusing such passages as a basis for rejection is unduly lengthening this prosecution with consequent cost. The Examiner is reminded of the requirement to "make a *thorough* investigation of the available prior art." 37 CFR 1.104 (a)(1)(emphasis added); see also MPEP 707. Moreover, "when a reference is complex . . . the particular part relied on must be designated" and "the pertinence of each reference, if not apparent, must be clearly explained." 37 CFR 1.104 (c)(2). In the present case, the passages offered have not been thoroughly examined or explained.

[2] To underscore the embodiment claimed, the term "native" has been added to Claims 1 and 9. This term is supported in various places in the specification, and is used in the examples with reference to particular insertion sites, *e.g.* the "natural" βB-βC loop (p. 20) and the "native" βB-βC loop (p. 21). This amendment is not made in acquiescence to the rejection or to overcome prior art, but to further the prosecution of claim directed to this embodiment. It must be stressed that other embodiments (e.g. where the insert is a replacement) are taught in the specification and applicants reserve the right to prosecute claims to these other embodiments in the future.

> "The nucleotide sequence of any suitable virus can be derived from a viral nucleic acid by modifying the coat protein coding sequence. The modification may be the removal of a coding sequence for at least a part of the viral coat protein. Alternatively, the nucleotide sequence can be synthesized such that it lacks at least a part of the viral coat protein coding sequence. A sufficient amount of the coding sequence is removed such that any coat protein which may be produced by the virus will be incapable of encapsidating the viral nucleic acid. In addition, the coat protein coding sequence may be modified by mutation such that the coat protein which is produced is incapable of encapsidating the viral nucleic acid. In each instance, as non-biologically functional protein is produced."

Again, nothing in the passage relates to insertion of a foreign peptide into the native coat protein. Indeed, this passage - even more clearly than the first - teaches the deletion or alteration of the coat protein to destroy function. Again, the present claims are directly opposite.

Even if these passages taught insertion of a foreign peptide into a native coat protein (which they do NOT!), the Examiner has made no effort to show that the text of these passages can be found in the '931 specification. This is improper.

The Examiner simply goes on to reject the claims, citing to portions of the published '931 patent - without checking to see (let alone establishing in the record) that these portions relied upon (from the '931 specification) can be found in an earlier parent. This is improper.

Applicants, on the other hand, have taken the trouble to check - and the results show that the Examiner's use of the '931 patent is not supported by the parent specification. Specifically, the Examiner cites to Column 12, lines 1-40 of the '931 issued specification as teaching the insertion of nucleic acid encoding a foreign peptide "into a plant viral nucleic acid sequence encoding a plant viral coat protein." (see the present Office Action, page 8). Attached hereto at Tab 1 is a comparison of the '931 specification text (from Column 11, lines 66-68 through Column 12, lines 1-22) with the corresponding text in the parent specification (found at page 27 of the 600,244 specification provided previously by the Examiner).[3] The text is not the same. Indeed, a critical change has been made. The parent specification (right hand side, italics) teaches *deleting the coding sequence* for the plant viral

[3] The Examiner did not point to the corresponding text. Applicants had to read through the parent specification in an attempt to find the corresponding text. This was done, not because it is applicants' burden, but because it appears the Examiner is unable or unwilling to make a careful comparison.

coat protein or *altering the native sequence*. It is only in the context of the ALTERED sequence that *insertion* is discussed.[4]

Importantly, one can see from the comparison (at Tab 1) that this language was changed in the CIP. Indeed, the "altered" and "deleted" language has been taken out, rendering the description to be *broader*. The Examiner cannot use a broader description in an issued patent filed AFTER the priority date of the present case. There is over 100 years of case law that warns about this problem:

> "Courts should regard with jealousy and disfavor any attempts to enlarge the scope of an application once filed, or of a patent once granted, the effect of which would be to enable the patentee to appropriate other inventions made prior to such alteration, or to appropriate that which has, in the meantime, gone into public use."

Chicago & N.W.Ry.Co. v. Sayles, 97 U.S. 554, at 563-564 (1878). Indeed, the Supreme Court has been vigilant in finding such changes to be new matter. For example, in *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938), the Supreme Court refused to permit an applicant to broaden an original disclosure that specified a "rigid web" to something that was not rigid, finding that it was impermissible "new matter":

> "Since rigidity is a relative term, the characterization of the structure as rigid must be taken as emphasizing rigidity rather than its opposite, flexibility, with special reference to the conditions to be encountered in the operation of the piston."

Schriber-Schroth, at pages 58-59). More recently, the Federal Circuit has recognized this problem and refused to accord claims drafted broadly to a generic cup the filing date of the parent application which disclosed a "conical cup". *See Tronzo v. Biomet*, 156 F.3d at 1158-59 (Fed. Cir. 1998). Applicants submit that these principles must apply here. The term "altered" emphasizes the need to change the biological function of the coat protein, rather than its opposite, the functional native coat protein. Broadening the disclosure to insertion into native, functional coat protein is "new matter."

Since the passage from the '931 patent contains new matter, it does not enjoy the filing date of the parent. Thus, the passage cannot be used as a basis for rejection. Since no

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[4] Thus, there is more here than "rearranging" the presentation of material. (Office Action, page 4, line 5). A careful reading of the parent specification as a whole shows that the emphasis was on rendering the capsid non-functional. This apparently changed when the CIP was filed.

other passages are offered by the Examiner to show a teaching for the insertion of the foreign peptide into the coat protein, the rejection based on the '931 specification cannot stand.

C. The Obviousness Rejection Must Fail

The Examiner makes an obviousness rejection based on a combination of the '931 patent with Untermohlen (the '976 patent). However, as shown above, the '931 patent cannot be combined with anything - it is not prior art.

D. Double Patenting

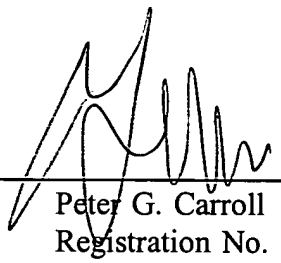
The Examiner has rejected Claims 9-16 under the judicially created doctrine of double patenting over claims 1-9 of U.S. Patent 5,874,087 stating that the claims are not patentably distinct over the claims of the '087. The Applicants respectfully disagree.

Nonetheless, provided Applicants' claims are otherwise found allowable, Applicants may split out Claims 9-16 into a separate application with the required Terminal Disclaimer. This would permit Claims 1-8 to issue. The Examiner is requested to call the undersigned prior to another Office Action in order to discuss this procedure.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that these grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.252.3353.

Dated: April 22, 2004



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The '931 Spec (CIP)

A second feature of the present invention is a recombinant plant viral nucleic acid which further comprises one or more non-native nucleic acid sequences capable of being transcribed in the plant host. The non-native nucleic acid sequence is placed adjacent one or the non-native viral subgenomic promoters and/or the native coat protein gene promoter depending on the particular embodiment used. The non-native nucleic acid is inserted by conventional techniques, or the non-native nucleic acid sequence can be inserted into or adjacent the native coat protein coding sequence such that a fusion protein is produced. The non-native nucleic acid sequence which is transcribed may be transcribed as an RNA which is capable of regulating the expression of a phenotypic trait by an anti-sense mechanism. Alternatively, the non-native nucleic acid sequence in the recombinant plant viral nucleic acid may be transcribed and translated in the plant host, to produce a phenotypic trait. The non-native nucleic acid sequence(s) may also code for the expression of more than one phenotypic trait. . The recombinant plant viral nucleic acid containing the non-native nucleic acid sequence is constructed using conventional techniques such that non native nucleic acid sequence(s) are in proper orientation to whichever viral subgenomic promoter is utilized.

Parent Spec (p. 27)

A second feature of the present invention is a chimeric nucleotide sequence which comprises a first nucleotide sequence and a second nucleotide sequence. The first sequence is capable of self-replication, is not capable of transmission and has substantial sequence homology to a viral nucleotide sequence, as described above. The second sequence is capable of being transcribed in a host. The second sequence is preferably placed adjacent a viral promoter, although a fusion protein may be produced which also has biological activity. Any viral promoter can be utilized, but it is preferred to use a promoter of the viral coat protein gene, *at least a part of the coding sequence of which has been deleted. In those instances where the coat protein coding sequence is altered but not deleted,* a viral promoter can be attached to the second sequence by conventional techniques or the second sequence can be inserted into or adjacent the coat protein coding sequence such that a fusion protein is produced. The second sequence which is transcribed may be transcribed as an RNA which is capable of regulating the expression of a phenotypic trait by an anti-sense mechanism. Alternatively, the second sequence in the chimeric nucleotide sequence may be transcribed and translated in the host, e.g., plant tissue, to produce a phenotypic trait. The second nucleotide sequence may also code for the expression of more than one phenotypic trait. The chimeric nucleotide sequence is constructed using conventional techniques such that the second nucleotide sequence is in proper orientation to the viral promoter.